DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2014

Katalyst Surgical, LLC
Ms. Meryl Koch
Quality Assurance and Regulatory Affairs Manager
754 Goddard Ave.
Chesterfield, MO 63005

Re: K140362
Trade/Device Name: Katalyst Revolver Laser Probes, Revolver Illuminated Laser Probes & Revolver Illuminated Probes
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF, HQB, MPA
Dated: August 8, 2014
Received: August 15, 2014

Dear Ms. Koch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140362

Device Name
Katalyst Revolver Laser Probes, Revolver Illuminated Laser Probes & Revolver Illuminated Probes

Indications for Use *(Describe)*
Revolver Laser Probes, Revolver Illuminated Laser Probes & Revolver Illuminated Probes are intended for use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments.

The Revolver Laser Probes can only be used with a medical laser at operating wavelengths of 500nm to 900nm. The Revolver assemblies containing illumination should only be used with the light wavelength range of 425nm to 700nm.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (K140362)

Manufacturer: Katalyst Surgical, LLC
754 Goddard Avenue
Chesterfield, MO 63005
636-399-0109 (phone)
636-787-0603 (fax)

Contact: Meryl Koch
Quality Assurance and Regulatory Affairs Manager
636-536-5950 (phone)
636-787-0603 (fax)
m.koch@katalystsurgical.com

Date Prepared: February 9th, 2013
Date Updated: September 10th, 2014

Device Trade Name: Revolver Laser Probes, Revolver Illuminated Laser Probes & Revolver Illuminated Probes

Common Name: (1) Ophthalmic photocoagulator, (2) Endoscope and accessories, and (3) Ophthalmic laser (accessory for)

Classification: (1) 21 CFR 886.4690; Ophthalmic photocoagulator, (2) 21 CFR 876.1500; Endoscope and accessories, and (3) 21 CFR 886.4390; Ophthalmic laser

Class: II

Product Code: HQF, HQB, and MPA

Indications For Use:
Revolver Laser Probes, Revolver Illuminated Laser Probes, and Revolver Illuminated Probes:

For use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments.

The Revolver Laser Probes can only be used with a medical laser at operating wavelengths of 500nm to 900nm. The Revolver assemblies containing illumination should be used with the light wavelength range of 425nm to 700nm.

Device Description:
The Katalyst Revolver Laser Probes are cables made out of one fiber optic (Single-Use), one laser adapter(Reusable), and one handle (Reusable) for surgeon manipulation, metal tubing extending from the handle which penetrates into the surgical site and protective sheath over the fiber.

The fiber for laser transmission is made out of glass, and is restricted for use within the wavelength range of 500nm to 900nm.

The fiber for illumination transmission is made out of either glass or plastic.

The illumination fiber (glass or plastic) is between 100 and 750 microns in size (measure based on the core diameter). The laser fiber (glass) is between 150 and 300 microns in size (measure based on the core diameter).

The tubing is provided in four different variations are referred to as straight, Curved, Flex-Curved, Steerable and Articulating. The configuration is chosen based on the surgeon requirements. The total length of the device is 8-10 feet.

In case of laser and illumination functionalities provided by the same probe, the common protective sheath runs for 1-2 feet, while both branches run for the remainder of the 8-10 feet with each branch having its own protective sheath and each branch ending with its own adapter. The same tubing will then hold within its internal diameter the laser fiber and the illumination fiber.

The Revolver Laser Probes can only be used with a medical laser at an operating wavelength range of 500nm to 900nm. The Revolver Illumination Probes can only be used with the light wavelength range of 425nm to 700nm.

Predicate Devices:
The Katalyst Revolver Laser Probe, Revolver Illuminated Laser Probe and Illuminated Probe were shown to be substantially equivalent to the previously cleared devices K121187-Katalyst Laser Probe and Illuminated Laser Probe.

Performance Testing Summary:
The testing for The Revolver Probes was conducted in accordance to All testing was performed in accordance with Attachment C of FDA Guidance on the Content and Organization for a Medical Laser, specifically, the "Specifications to be used in Establishing the Substantial Equivalence" for accessories and other information, is summarized below:

The data presented in Table 6-1 is the output power ratings of illumination and laser surgical machines and the input power capacity of the optical fibers used in the Laser and Illuminated Laser Probes.

Table 6-1: Power Specifications for Katalyst Laser and Illuminated Laser Probes

Optical Fiber Type	Typical Maximum Machine Output	Typical Machine Output Setting	Optical Fiber Maximum Input Power Capacity
Illumination	28 mW	14 mW	350 W*

Laser	2.5 W	300 mW	314 kW
*Plastic optical fiber.			

Table 6-1A: Power Specifications for Glass Fiber

Optical Fiber Type	Typical Maximum Machine Output	Typical Machine Output Setting	Optical Fiber Maximum Input Power Capacity
Glass	2.5 W	300 mW	314 kW

Table 6-1B: Power Specifications for Plastic Fiber

Optical Fiber Type	Typical Maximum Machine Output	Typical Machine Output Setting	Optical Fiber Maximum Input Power Capacity
Plastic	28 mW	14 mW	350 W

Additionally, light transmission data was collected for the Katalyst Revolver Illuminated Laser Probes, Revolver Illuminated Probes and the predicate Illuminated Laser Probes.

The results show that the Katalyst Illuminated Probes will perform in the same manner and efficacy as the predicate, thus causing no extra risk to the patient and/or the user.

	Light Output in Lumens (average)	% Difference
Katalyst Surgical Probes	26.3	0.38%
Katalyst Revolver Illuminated Probes	26.2	

Biocompatibility testing:
Biocompatibility testing was performed on the probes per ISO 10993. Testing was performed by Toxikon, Inc. The testing was conducted on the materials that are in contact with the patient, being the fibers (glass and plastic), and metal tubing, simulating the actual device. The testing successfully determined the Katalyst Revolver Probes to be biocompatible.

Substantial Equivalence:
Bench testing performed on this device and compared to the predicate indicates that the Katalyst Revolver Laser Probes, Revolver Illuminated Laser Probes and Revolver Illuminated Probes are substantially equivalent to predicate devices. Bench testing of the Katalyst Revolver Probes was performed in accordance with FDA Guidance on the Content and Organization for a Medical Laser. Biocompatibility testing was performed per ISO 10993. Sterilization development, validation, and control were performed in accordance with ISO 11135-1. Product shelf-life was established in accordance with ASTM Standard #F

1980-09 (2011) and packaging integrity was established in accordance with ASTM F 1929-04 and ASTM F881F88M-09. Optical radiation safety testing was performed in accordance with ISO 15752 and ISO 15004-2.

SUMMARY OF EQUIVALENCE

FDA File Reference No.	510(k) No. K021696 for Laser	510(k) No. K050807 for Illumination
TECHNOLOGICAL CHARACTERISTICS	Comparison Result	Comparison Result
Indications for Use	Identical	Identical
Target Population	Identical	Identical
Design	Similar	Similar
Optical Output	Identical	Identical
Materials	Identical	Identical
Performance	Identical	Identical
Sterility	Identical	Identical
Biocompatibility	Identical	Identical
Anatomical Sites	Identical	Identical
Human Factors	Identical	Identical
Energy Used and/or Delivered	Similar	Similar
Compatibility with Environment and Other Devices	Identical	Identical
Where Used	Identical	Identical
Standards Met	Identical	Identical
Electrical Safety	Identical (not applicable)	Identical (not applicable)
Thermal Safety	Identical (not applicable)	Identical (not applicable)
Radiation Safety	Identical (not applicable)	Identical (not applicable)

The technological characteristics are identical to the predicate device, in terms of the indication for use, target population, optical output, materials, performance, sterility, biocompatibility, anatomical sites, human factors, compatibility with environment and other devices. The electrical, thermal and radiation safety is identical, because it's not applicable to any of the devices.

The Revolver Probes design is similar to the predicate devices. The Revolver Probes comes four different gauges (20g, 23g, 25g, 27g) and four different tip configuration (i.e., straight, curved, flex-curved, and steerable). The tip configuration is straight or curved for the predicate devices. The difference in tip variations of the Katalyst Revolver Probes and the straight or curved tips of the predicate devices does not affect the safety or effectiveness of the Katalyst Revolver Probes when used as indicated. A surgeon may use any variation of the tip, straight, curved, flex-curved and steerable: in an identical manner; (2) to perform an identical surgical procedure; and (3) to achieve the same surgical result.

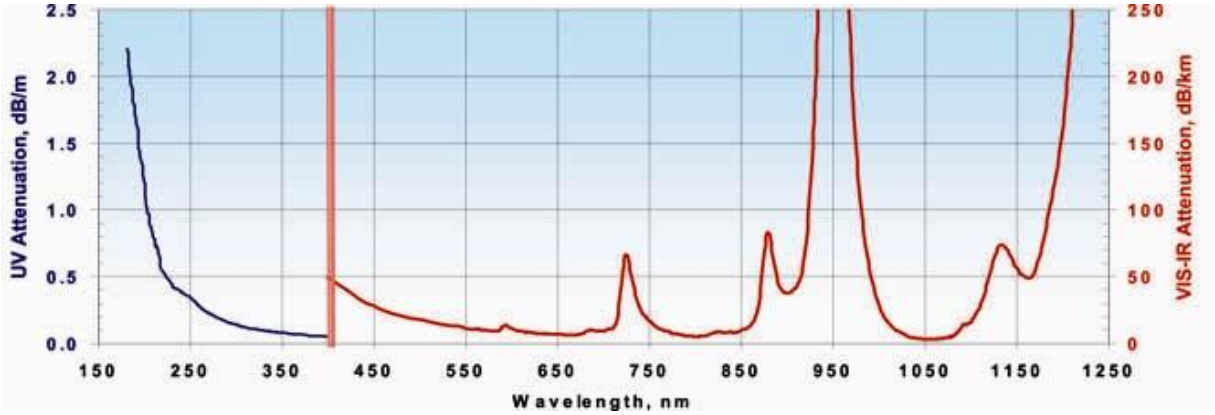
The predicate devices come in 20g, 23g, and 25ga in laser probes, and 20ga in Illuminated laser probes. Katalyst Revolver Probes come in 20ga, 23ga, 25ga, and 27ga, for laser, illumination and laser illumination probes. The addition of the various gauge sizes does not affect the safety and effectiveness of the device. All the micron sizes are within the range of the pervious cleared predicate device.

Table 3-1: Materials and Sizing of Optical Fibers

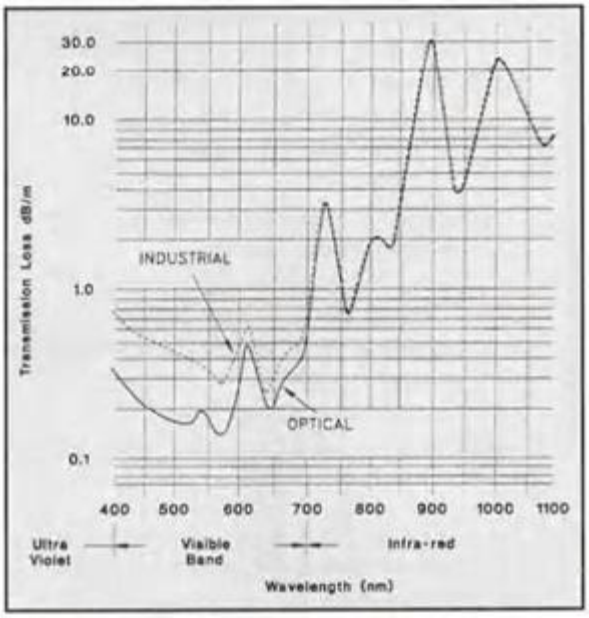
Type		Material		Size (microns)
Laser		Glass	SILICA/SILICA	150-300
Laser/Illumination (plastic illumination fibers)	Laser	Glass	SILICA/SILICA	150-300
	Illumination	Plastic	Acrylic	100-500
Laser/Illumination (glass illumination fibers)	Laser	Glass	SILICA/SILICA	100-300
	Illumination	Glass	SILICA/SILICA	100-500

Gauge	Laser Fiber		Illumination Fiber		Laser illumination fiber	
	Core/ Cladding Diameter	Attenuation/ transmission	Core/ Cladding Diameter	Attenuation/ transmission	Core/ Cladding Diameter	Attenuation/ transmission
20 ga	200 µm ± 4 µm 220 µm ± 4 µm	See Below	486 µm ± 6% 14 µm ± 6%	See Below	390 µm ± 6% 10 µm ± 6%	See Below
23 ga	200 µm ± 4 µm 220 µm ± 4 µm	See Below	240 µm ± 9% 10 µm ± 9%	See Below	240 µm ± 9% 10 µm ± 9%	See Below
25 ga	150 µm ± 3 µm 165 µm ± 3 µm	See Below	240 µm ± 9% 10 µm ± 9%	See Below	190 µm ± 9% 10 µm ± 9%	See Below
27 ga	150 µm ± 3 µm 165 µm ± 3 µm	See Below	240 µm ± 9% 10 µm ± 9%	See Below	140 µm ± 9% 10 µm ± 9%	See Below

Typical Attenuation for Glass Fiber



Attenuation for Plastic Fiber
(Katalyst Fiber is Optical Grade)



Furthermore, the predicate devices are single-use devices. The revolver probes are assembled with single-use, and reusable components. Revolver probes comprise three components, handle, fiber and an adapter. The handle and adapter are reusable and are provided non-sterile. The replaceable fiber is a single-use component, and is provided sterile. This change from the predicate device does not have any impact on the safety and effectiveness of the device. The predicate devices and The Revolver Probes are intended as accessories to devices used to coagulate or cut tissue of the eye, orbit, or surrounding skin by a laser beam and to provide illumination during vitroretinal surgery. Therefore, The Revolver Probes are substantially equivalent to the previously cleared devices.

Conclusion

The Katalyst Revolver Probes were shown to be substantially equivalent to previously cleared devices with respect to intended use, indications for use, technological characteristics, performance characteristics, and biocompatibility.